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09/733,215	12/08/2000	Badri N. Prasad	6944	3483

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EXAMINER	
PASS, NATALIE	
ART UNIT	**PAPER NUMBER**
3686	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/733,215	PRASAD ET AL.	
	Examiner	Art Unit	
	Natalie A. Pass	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the responses filed 25 November 2008. Claims 1-50 have been cancelled. Claims 51-52 have been newly added. Claims 51-52 remain pending.

Claim Objections

2. Claim 51 is objected to because of the following informalities: Claim 51 recites "(c) whether the member incurrent" in line 19. For the purpose of applying art, Examiner assumes this claim to recite "(c) whether the member incurred." Appropriate correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 51-52 are rejected under 35 U.S.C. §101.

A) As per claims 51-52, these appear to be directed toward a a computer-implemented method or process for high risk member identification. Based on Supreme Court precedent, and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr,* 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson,* 409 U.S. 63, 70 (1972); *Cochrane v. Deener,* 94 U.S. 780,787-88 (1876).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state.

In the instant application, Appellant's method steps fail the first prong of the new Federal Circuit decision since they are not required to be tied to another statutory class and can be performed without the use of a particular apparatus. Furthermore, the method steps fail to unambiguously require transformation of underlying subject matter to a different state or thing. The mere manipulation and production of non-functional descriptive material (i.e., "relative risk rankings") is not a transformation because a relative risk ranking is not statutory subject matter. Thus, claims 51-52 are non-statutory since they are not requisitely tied to another statutory class and they do not requisitely transform underlying subject matter to a different state or thing.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Newly added claim 52 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) Claim 52 recites limitations that are new matter, and are therefore rejected. The added material which is not supported by the original disclosure is as follows:

- "wherein the intervention agent may filter the displayed subset members by … [...] ... products," as disclosed at line 2.

35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. "New matter" constitutes any material which meets the following criteria:

a) It is added to the disclosure (either the specification, the claims, or the drawings) after the filing date of the application, and

b) It contains new information which is neither included nor implied in the original version of the disclosure. This includes the addition of physical properties, new uses, etc.

In particular, the Examiner was unable able to find any support for this newly added language within the specification as originally filed on 8 December 2000. Applicant is respectfully requested to clarify the above issues and to specifically point out support for the newly added limitations in the originally filed specification and claims.

Applicant is required to cancel the new matter in the reply to this Office Action.

7. If Applicant continues to prosecute the application, revision of the specification and claims to present the application in proper form is required. While an application can, be

amended to make it clearly understandable, no subject matter can be added that was not disclosed in the application as originally filed on 8 December 2000.

8. The rejection of claims 34-50 under 35 U.S.C. 112, first paragraph for claiming new matter is hereby withdrawn due to the amendment filed 25 November 2008.

9. The rejection of claims 34, 42, 43 under 35 U.S.C. 112, second paragraph for being indefinite is hereby withdrawn due to the amendment filed 25 November 2008.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lash (2001/0020229 A1).

(A) As per newly added claim 51, Lash teaches a computer-implemented high risk member identification method, comprising a computer performing the following:

identifying a group of members to be analyzed, each group member having an associated relative risk value, wherein the relative risk value for each member is a function of predicted future healthcare resource utilization for the member (Lash; Abstract, paragraphs [0007]-[0012],

[0021]- [0022], [0041] -[0042]); Examiner interprets Lash's teachings of "[t]he stored program analyzes the subset of claims data according to a probability equation created by the regression analysis, which equation is based at least in part on the sum of each of the high relevance claims variables multiplied by corresponding weighing coefficients. The stored program computes probability values for each patient which are indicative of the likelihood that the patient will acquire high service utilization characteristics. For instance, such high service use characteristics can include the patient suffering one or more high-cost medical events or episodes, or the patient becoming a high user of services overall relative to other patients" (Lash; paragraph [0007]) to teach a form of "identifying a group of members to be analyzed, each group member having an associated relative risk value, wherein the relative risk value for each member is a function of predicted future healthcare resource utilization for the member;"

filtering the group members to identify members having an associated relative risk value that exceeds a threshold value of relative risk, thereby identifying a subset of the group members for potential intervention (Lash; paragraphs [0022], [0036],[0055]); Examiner interprets Lash's teachings of "multivariate statistical modeling to develop multiple-variable predictive models for determining the likelihood of a particular member of a health care plan will acquire high use characteristics, particularly those with attendant high costs, such as suffering frequent high-cost medical episodes or utilizing health care resources in such a way so as to become a high-cost patient overall relative to other patients. The present invention evaluates both the presence and absence of certain events as a measure of a patient's future risk utilizing statistical tools" (Lash; paragraph [0022]) together with Lash's teachings of "[o]nce the high use patients are determined,

a threshold value can be set by the MCO, such as 50%, and the MCO can then target such high use patients falling above the threshold with preemptive intervention strategies to attempt to change the likely course of the disease … [...] ... " (Lash; paragraph [0055]) to teach a form of "filtering the group members to identify members having an associated relative risk value that exceeds a threshold value of relative risk, thereby identifying a subset of the group members for potential intervention;"

creating a database of claim data for the subset members, wherein the database includes all medical diagnoses and healthcare utilization patterns for each subset member during a focus period, including any physician claims, facility claims and pharmacy claims associated with each subset member during the focus period (Lash; Table 2, paragraphs [0007], [0010], [0023], [0036]-[0038], [0049]-[0050], [0053]-[0054], [0057], [0059]); Examiner interprets Lash's teachings of "[d]atabase 10 contains information about each member patient in a MCO or other organization, including insurance claims data and medical encounter data for a given period of time. Such data preferably includes information representing the patient's prior utilization of medical and pharmacy services, and may also include the cost of these services. For example, the claims data may include, on a yearly basis, information such as the number of hospital in-patient days for a particular illness, the total number of hospital in-patient days, the number of ER visits, the number of prescriptions filled, the presence of a specific disease or condition related diagnosis, etc. … [...] ... Database 10 can store information for multiple time periods … [...] ..." (Lash; paragraph [0024]) together with Lash's teachings of "[o]f course, other claims

data and encounter information can also be stored and used in the patient database" (Lash; paragraph [0049]) to teach a form of this limitation;

analyzing the claim data of each subset member to ascertain the presence or absence of each of a plurality of intervenability factors present to the subset member, (Lash; paragraph [0050]) wherein the intervenability factors for each subset member are identified based upon aspects of each subset member's care history that are amenable to intervention by an intervention agent (Lash; paragraph [0055]); Examiner interprets Lash's teachings of "[o]nce the high use patients are determined, a threshold value can be set by the MCO, such as 50%, and the MCO can then target such high use patients falling above the threshold with preemptive intervention strategies to attempt to change the likely course of the disease … [...] ... " (Lash; paragraph [0055]) to teach a form of this limitation; and wherein the intervenability factors include:

(a) whether the member visited the emergency room during the focus period (Lash; paragraphs [0010], [0057]),

(b), whether the member had any in-patient hospital admissions during the focus period (Lash; paragraphs [0049], [0057]),

(d) whether the member visited more than three different provider specialists during the focus period (Lash; paragraph [0049], [0057]);

(e) whether the member was prescribed multiple pharmaceuticals during the focus period (Lash; paragraph [0049], [0057]),

(f) whether the member has no "nearby" (reads on "appropriate") provider for a chronic episode during the focus period (Lash; paragraphs [0022], [0044], [0049]); Examiner interprets

Lash's teachings of "[t]hey might also be counselled to make precautionary visits to a clinic within their zip code … [...] ... " (Lash; paragraph [0044]) together with Lash's teachings of "[t]he present invention evaluates both the presence and absence of certain events as a measure of a patient's future risk utilizing statistical tools" (emphasis added) (Lash; paragraph [0022]) to teach a form of "the member has no appropriate provider for a chronic episode during the focus period,"

(g) whether the member missed a target intervention during the focus period (Lash; paragraphs [0022], [0040], [0045]), Examiner interprets Lash's teachings of "[o]ver the next time period of interest, the utilization of medical service by the patient is monitored (step 84) so that the patient record includes not only the intervention that was attempted, but the patient's use of services … [...] ..." (Lash; paragraph [0045]) together with Lash's teachings of "[t]he present invention evaluates both the presence and absence of certain events as a measure of a patient's future risk utilizing statistical tools" (emphasis added) (Lash; paragraph [0022]) to teach a form of "whether the member missed a target intervention during the focus period," and

(h) whether the member fails to obtain fills of prescribed medication during the focus period (Lash; paragraphs [0022], [0040], [0045]), Examiner interprets Lash's teachings of "[o]ver the next time period of interest, the utilization of medical service by the patient is monitored (step 84) so that the patient record includes not only the intervention that was attempted, but the patient's use of services … [...] ..." (Lash; paragraph [0045]) together with Lash's teachings of "[t]he present invention evaluates both the presence and absence of certain events as a measure of a patient's future risk utilizing statistical tools" (emphasis added) (Lash;

paragraph [0022]) together with Lash's teachings of "they do not take their medication" (Lash; paragraph [0040]) to teach a form of "whether the member fails to obtain fills of prescribed medication during the focus period,"

assigning each subset member a number of intervenability factors representing a total number of the intervenability factors present in the subset member's claim data (Lash; paragraphs [0010], [0022], [0040], [0044]-[0045], [0049], [0050], [0055]), [0057]);

assigning a relative risk ranking to each subset member based upon the subset member's associated relative risk value and the number of intervenability factors assigned to the subset member (Lash; Abstract, paragraphs [0007]-[0012], [0021]- [0022], [0041] -[0042]); Examiner interprets Lash's teachings of "[t] he stored program analyzes the subset of claims data according to a probability equation created by the regression analysis, which equation is based at least in part on the sum of each of the high relevance claims variables multiplied by corresponding weighing coefficients. The stored program computes probability values for each patient which are indicative of the likelihood that the patient will acquire high service utilization characteristics. For instance, such high service use characteristics can include the patient suffering one or more high-cost medical events or episodes, or the patient becoming a high user of services overall relative to other patients" (Lash; paragraph [0007]) to teach a form of "assigning a relative risk ranking to each subset member based upon the subset member's associated relative risk value and the number of intervenability factors assigned to the subset member;"

determining one or more top medical episodes driving risk of each subset member, wherein the top medical episodes are determined by examining the subset member's claim data by diagnosis code or medical episode to determine which of the subset member's medical conditions has the highest associated cost (Lash; Figure 4, paragraphs [0022], [0041] - [0042], [0057]); Examiner interprets Lash's teachings of "rigorous, multivariate statistical modeling to develop multiple-variable predictive models for determining the likelihood of a particular member of a health care plan will acquire high use characteristics, particularly those with attendant high costs, such as suffering frequent high-cost medical episodes or utilizing health care resources in such a way so as to become a high-cost patient overall relative to other patients. The present invention evaluates both the presence and absence of certain events as a measure of a patient's future risk utilizing statistical tools" (emphasis added) (Lash; paragraph [0022]) together with Lash's teachings of "[i]n the first step of regression analysis (step 66B of FIG. 3B), a regression model is built using all of the potentially predictive variables which have an effect on the patient's future likelihood of developing a pattern of high use of the services, particularly high-cost occurrences or episodes. Such variables are all claims variables … [...] ... " (Lash; paragraph [0057]) to teach a form of this limitation;

displaying (a) a list of the subset members ordered by respective relative risk rankings and (b) the relative risk value for each subset member (Lash; paragraphs [0037], [0048]);

receiving a selection of one or more displayed subset members by an intervention agent (Lash; paragraph [0037], 0048]); and

displaying demographic information (Lash; Figure 4, Item 81, paragraphs [0037], [0043], [0048]), a utilization summary (Lash; paragraphs [0037], [0048]-[0049]), risk factors including behavioral risk factors and self-care characteristics (Lash; paragraphs [0037]-[0038], [0048]-[0049], [0058]- [0059]), the intervenability factors (Lash; paragraphs [0022], [0036]-[0037], [0048]-[0049], [0050], [0055], [0057]), and the one or more top medical episodes for each subset member selected by the intervention agent (Lash; Figure 4, paragraphs [0022], [0037], [0041] - [0042], [0048], [0057]).

Lash fails to explicitly disclose

(c) whether the member incurrent [*sic*] any out-of-network costs during the focus period.

However Lash teaches"[a]ny number of claims variables can be used depending on what claims information is tracked by the MCO" (Lash; paragraph [0024]) and Lash teaches "[i]n this application, many different claims variables and encounter data (e.g., an ER visit) are available for potential use in the model. Such potential variables may include, among others, the patient's age at the end of an index year (AGE); the patient's sex (SEX); the number of hospital in-patient days for respiratory-related admissions involving ICU care at any time during the admission (ICUDAY); the number of hospital in-patient days … [...] ... the number of prescription drug claims (RXCNT) … [...] ... Of course, other claims data and encounter information can also be stored and used in the patient database" (Lash; paragraph [0049]) and Lash teaches "a regression model is built using all of the potentially predictive variables which have an effect on the patient's future likelihood of developing a pattern of high use of the services, particularly high-cost occurrences or episodes. Such variables are all claims variables (and possibly some

demographic variables) suspected of having some positive or negative effect on the outcome variable" (Lash; paragraph [0057]).

Examiner submits that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the method of LASH to include these limitations with the motivations of "accurately predict[ing] those patients who are most likely to incur future clinical complications and the high utilization of services and costs associated with those events" and allow "the MCO to target the proper populations of patients who will likely be high service user patients so that preventative or other medical care can be directed to them in order to reduce the risk that they will actually become high users of medical services" (Lash; paragraphs [0005]-[0006]).

(B) As per newly added claim 52, Lash teaches a method as analyzed and disclosed in claim 51 above

wherein the intervention agent may filter the displayed subset members by zipcode, county, group numbers, products, member ID or member names. (Lash; paragraphs [0037], [0042]-[0043], [0050]).

Response to Arguments

12. Applicant's arguments on pages 6-7 of the response filed 25 November 2008 with respect to claims 51-52 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

> A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. **Any response to this final action should be mailed to**:

Box AF
Commissioner of Patents and Trademarks
Washington D.C. 20231

or faxed to: (571) 273-8300.

For formal communications, please mark "EXPEDITED PROCEDURE".

16. For informal or draft communications, please label "PROPOSED" or "DRAFT" on the front page of the communication and do NOT sign the communication. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie

A. Pass whose telephone number is (571) 272-6774. The examiner can normally be reached on 9-6:30 Monday - Thursday and alternate Fridays.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/N. A. P./
Examiner, Art Unit 3686
February 20, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686